K021699

AUTOLENS® Inc.
1440 Atteberry Lane
San Jose, California 95131-1410
Phone: (408) 432-0580

DEC 16 2002

510(k) Summary Statement

SUBMITTER:

Submitted on behalf of:

Company Name:	AUTOLENS®, Inc.
Address:	1440 Atteberry Lane San Jose, California 95131-1410
Phone:	(408) 432-0580
Fax:	(408) 432-8252

CONTACT PERSON:	Richard E. Lippman, O.D., F.A.A.O. Official Representative and Correspondent R.P. Chiacchierini & Associates, LLC 15825 Shady Grove Road Suite 30 Rockville, Maryland 20850
Phone:	(240) 683-3738
FAX:	(240) 683-9236

DATE SUMMARY PREPARED:	November 15, 2002
TRADE NAME:	AUTOLENS® System: Comprised of the AUTOLENS® Automatic Contact Lens Cleaning Accessory and AUTOLENS® Multipurpose Solution
COMMON NAME:	contact lens cleaning accessory device
CLASSIFICATION:	Class II: LYL 886 LPN 886

ESTABLISHMENT REGISTRATION: PENDING

SUBSTANTIALLY EQUIVALENT TO:

The AUTOLENS® System, comprised of the AUTOLENS® Automatic Contact Lens Cleaning Accessory and AUTOLENS® Multipurpose Solution is substantially equivalent to the following device accessories:

K982115	LensServer Automatic Contact Lens Cleaning Accessory cleared 1/13/99
K974724:	Lens Comfort Contact Lens Accessory cleared 3/2/98
K852386:	"SOFT MATE® , Automatic Contact Lens Cleaning Unit" cleared 9/4/85
K964222:	Acu-Clens Cleaning System for Contact Lenses- Cleared 12/20/1996

Each of these accessories was cleared in conjunction with contact lens solutions for cleaning and disinfection, comprising a contact lens cleaning system. The AUTOLENS® Automatic Contact Lens Cleaning System is indicated as an aid for cleaning as an accessory for all contact lenses when used with the AUTOLENS® Brand MULTI-PURPOSE Contact Lens Solution.

All of the predicate cleaning units act by similar tumbling action or ultrasonic agitation of lenses by directing the flow of contact lens solution around the contact lenses while immersed in the solution. The accessory devices all work in conjunction with approved contact lens cleaning and disinfection solutions. The AUTOLENS® Automatic Contact Lens Cleaning System functions in an equivalent manner. The Directions for Use describe the sequential actions of the tumbling cleaning device, a rinse step, and a storage soaking step for disinfection in AUTOLENS® Multipurpose Solution.

DESCRIPTION of the DEVICE:

The device is a holder, cleaning and disinfection system for contact lenses. It consists of a contact lens holder, bottle, cap and base. A separate battery operated tumbler device is integral to the system. It is designed to slowly tumble the bottle assembly including contact lens solution to effect cleaning of contact lenses.

The lens holder is a single piece molded plastic device including hinged snap closure covers to contain each contact lens separately. An easily identifiable, raised letter "R" and "L" is included adjacent each closure receptacle to allow clear identification for right and left contact lenses placed within the lens holder. The lens holder contains openings to sufficiently allow the free flow of solution to circulate on all surfaces of the contact lens during the cleaning process.

The bottle is made of molded plastic and is of oval shape to facilitate the flow of solution over the lens holder and lenses during operation. The bottle is of sufficient size to contain the lens holder and 8 ml. of contact lens solution to cover the contact lenses at all times during operation and storage. The bottle is designed to hold the contact lens holder securely to ensure its rotation as the bottle spins during operation. The bottle is designed with a fluid-tight, screw closure cap. The lens holder, bottle, cap and base are made of polypropylene resin plastic.

The tumbler device is a battery powered unit operating at 1.5 volts utilizing three "AA" batteries. A plastic housing is molded to contain a small electrical motor, tumbler drive, on/off switch, batteries and a battery door to easily replace batteries. A cradle is molded within the shape of the housing to contain the assembled lens holder bottle. The drive shaft is connected to the motor inside the base housing.

When the device is turned on at the switch, the battery operated electrical motor turns the extended drive shaft. The bottle assembly resting upon the drive shaft turns in unison. The mechanical action of the bottle assembly on the drive shaft provides for a rotation of approximately 10 RPM.

INDICATIONS FOR USE:

The AUTOLENS ® Automatic Contact Lens Cleaning Accessory is indicated for the cleaning of soft (hydrophilic), rigid gas permeable (RGP) and hard (PMMA) contact lenses when used with AUTOLENS® Multipurpose Solution. This automatic contact lens cleaning accessory cleans contact lenses without digital rubbing. The AUTOLENS® Automatic Contact Lens Cleaning Accessory may be used as a receptacle for chemical disinfection with AUTOLENS® Multipurpose Solution.

AUTOLENS® Multipurpose Solution is indicated for use in cleaning, rinsing, chemical (not heat) disinfecting and protein removal, storing soft (hydrophilic), rigid gas permeable fluoro-silicone acrylate and silicone acrylate) and PMMA contact lenses as recommended by your eye care practitioner.

ACTIONS:

The AUTOLENS ® System provides for cleaning of soft (hydrophilic), rigid gas permeable (RGP), or hard (PMMA) contact lenses by means of the automatic slow rotation tumbling action of the contact lenses immersed in AUTOLENS® MULTI-PURPOSE SOLUTION within a bottle container, followed by a rinsing step and soaking and disinfection step in AUTOLENS® Multipurpose Solution.

The accessory contact lens cleaning system is recommended for use with AUTOLENS ® Brand MULTI-PURPOSE SOLUTION to clean, rinse, disinfect and store soft (hydrophilic), hard (PMMA), or rigid gas permeable (RGP) contact lenses. The AUTOLENS® Brand MULTI-PURPOSE SOLUTION has been licensed from a commercially cleared product as private label manufacturer under the AUTOLENS ® Brand label. Labeling instructions and labels have been provided for the private label licensed solution.

A minimum of four hours operational use is recommended to effect the cleaning of contact lenses. The AUTOLENS ® System effectively cleans contact lenses automatically without the need for digital rubbing or manual hand cleaning.

TOXICITY TESTING

A battery of toxicology tests were conducted on the plastic components of the system to determine the potential for problems with biocompatibility. The tests included Cytotoxicity, Ocular Irritation, and Systemic Toxicity. The results of each of the tests conducted on the device components did not indicate any response that would raise concern regarding the safety of the components for biocompatibility when tested in laboratory animals.

EFFECTIVENESS TESTING for the AUTOLENS®

A bench testing protocol was employed to test the AUTOLENS® device with the appropriately recommended Multi-Purpose contact lens solution for a measure of solution pH and temperature gain in order to ascertain solution stability over the 4 hour recommended soak-time for cleaning. The protocol called for measuring three (3) test devices with solution immersed in the lens holder bottle. In all cases, the final pH of the test

solution in the chamber was the same as the pH at the start of the procedure concluding that no change of solution was witnessed during the operation of the device under the directions of use.

A measure of the temperature at the start and completion of the procedure was made to determine whether any heat transfer occurred to raise the temperature beyond that which would be safe for stability of the supporting cleaning and disinfection solution. The results indicate that the temperature rise was minimal.

Additional compatibility testing for recommended wetting drops and the AUTOLENS® Brand MULTI-PURPOSE Solution was conducted. The results indicate that the solutions were deemed compatible and without precipitate formation.

CLINICAL INFORMATION

Clinical studies were deemed unnecessary as the solution used in the AUTOLENS® System is already cleared for marketing as a cleaning, rinsing, disinfection, and storage solution for soft, RGP, and hard contact lenses.

LABELING

The AUTOLENS® System is provided to the user with instructions for use. Additionally, the Package Insert for the AUTOLENS® Brand MULTI-PURPOSE Solution is provided. These materials are also available from the company. The address is as follows:

AUTOLENS® Inc.
1440 Atteberry Lane
San Jose, California 95131-1410
Phone: (408) 432-0580

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2002

Autolens, Inc.
c/o Richard E. Lippman, O.D.
R.P. Chiacchierini and Associates
15825 Shady Grove Rd., Suite 30
Rockville, MD 20850

Re: K021699
Trade/Device Name: Autolens System comprised of the Autolens Automatic Contact Lens Cleaning Accessory and Autolens Brand Multipurpose Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LYL; LPN
Dated: November 15, 2002
Received: November 18, 2002

Dear Dr. Lippman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications Statement

510(k) Number (if known) K021699
Device Name: AUTOLENS® System comprised of the AUTOLENS® Automatic Contact Lens Cleaning Accessory and AUTOLENS® Multipurpose Solution

Indications for Use:

The AUTOLENS ® Automatic Contact Lens Cleaning Accessory is indicated for the cleaning of soft (hydrophilic), rigid gas permeable (RGP) and hard (PMMA) contact lenses when used with AUTOLENS® Multipurpose Solution. This automatic contact lens cleaning accessory cleans contact lenses without digital rubbing. The AUTOLENS® Automatic Contact Lens Cleaning Accessory may be used as a receptacle for chemical disinfection with AUTOLENS® Multipurpose Solution.

AUTOLENS® Multipurpose Solution is indicated for use in cleaning, rinsing, chemical (not heat) disinfecting and protein removal, storing soft (hydrophilic), rigid gas permeable (fluoro-silicone acrylate and silicone acrylate) and PMMA contact lenses as recommended by your eye care practitioner.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over -The-Counter Use X

(Optional Format 1-2-96)

Myra Smith
(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K021699